

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

EASTERN DIVISION

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5 INTERNATIONAL DAIRY FOODS :
ASSOCIATION, :
: :
6 PLAINTIFF, :
: :
7 VS. : CASE NO. 2:08-cv-628
: :
8 ROBERT J. BOGGS, :
9 SOLELY IN HIS OFFICIAL CAPACITY :
AS OHIO DIRECTOR OF AGRICULTURE, :
10 : :
11 DEFENDANT. :
12 : :
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12 ORGANIC TRADE ASSOCIATION, :
13 : :
14 PLAINTIFF, :
15 : :
16 VS. : CASE NO. 2:08-cv-629
17 : :
18 ROBERT J. BOGGS, :
19 IN HIS OFFICIAL CAPACITY AS :
OHIO DIRECTOR OF AGRICULTURE, :
20 : :
21 DEFENDANT. :
22 - - -

INITIAL PRELIMINARY INJUNCTION CONFERENCE

20 BEFORE THE HONORABLE JAMES L. GRAHAM, UNITED STATES DISTRICT JUDGE,
SOUTHERN DISTRICT OF OHIO, EASTERN DIVISION, SITTING AT COLUMBUS,
21 OHIO, ON JULY 1, 2008.

22 APPEARANCES:

23 CHARLES J. ENGLISH, JR., ESQ.,
24 CLAY HUFF, GENERAL COUNSEL,
JOHN MCDONALD, ESQ.,

25 ON BEHALF OF PLAINTIFF INTERNATIONAL DAIRY FOODS ASSOCIATION.

1 RANDALL J. SUNSHINE, ESQ.,
2 MICHAEL J. KING, ESQ.,

3 ON BEHALF OF PLAINTIFF ORGANIC TRADE ASSOCIATION.

4 JAMES R. PATTERSON, ASSISTANT ATTORNEY GENERAL,
5 WILLIAM J. COLE, ASSISTANT ATTORNEY GENERAL,
6 JOHN WILLIAMS, ASSISTANT ATTORNEY GENERAL,

7 ON BEHALF OF DEFENDANT ROBERT J. BOGGS.

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25 LAURA L. SAMUELS
OFFICIAL FEDERAL COURT REPORTER

Tuesday Morning Session

July 1, 2008

4 THE COURT: Let's go around the table, and we will have
5 all the counsel formally enter their appearances.

6 MR. ENGLISH: Good morning, Your Honor. My name is
7 Charles English. I am with the law firm of Thelen, Reid, Brown,
8 Raysman & Steiner in Washington, D.C., representing the
9 International Dairy Foods Association, plaintiff. And I believe I
10 have *pro hac* papers on file.

11 MR. HUFF: Good morning, Your Honor. My name is Clay
12 Huff, and I am the general counsel with the International Dairy
13 Foods Association based in Washington, D.C.

14 MR. MCDONALD: Good morning, Your Honor. I am John
15 McDonald with Schottenstein, Zox & Dun. I'm here as local counsel
16 on behalf of the Dairy Foods Association.

17 MR. SUNSHINE: Good morning, Your Honor, Randy Sunshine,
18 from the law firm of Liner, Yankelevitz, Sunshine & Regenstreif in
19 Los Angeles. I have also filed *pro hac* papers on behalf of the
20 Organic Trade Association.

21 MR. KING: Good morning, Your Honor, Michael King from
22 Dinsmore & Shohl here in Columbus, serving as local counsel with
23 Randy Sunshine for the Organic Trade Association.

24 MR. WILLIAMS: Your Honor, John Williams from the
25 Attorney General's office. My section represents Director Boggs

1 and the Department of Agriculture.

2 MR. COLE: Your Honor, I'm Bill Cole with the Attorney
3 General's office on behalf of the Department of Agriculture and
4 Director Boggs.

5 MR. PATTERSON: Good morning, Your Honor, Jim Patterson,
6 Assistant Attorney General, trial attorney for Director Boggs in
7 both cases that have been filed yesterday.

8 THE COURT: Very well, thank you, counsel.

9 This is the case of International Dairy Foods Association
10 and others against Robert J. Boggs, Director of the Ohio
11 Department of Agriculture. This case was filed in our court
12 yesterday morning with a request for a temporary restraining
13 order. And we have a local rule that requires an initial
14 conference between the Court and counsel before the Court takes
15 any action on a request for temporary injunctive relief. So we
16 are convened here this morning pursuant to that rule.

17 But I think this is a case in which we might expand the
18 nature of the conference perhaps to include discussion of an
19 appropriate scheduling order in this case to accomplish all of the
20 necessary preparation for a hearing.

21 As I looked over the papers, it became apparent this was
22 not a case in which there was an immediate urgency in that, as so
23 often the case, where we're confronted with having to preserve a
24 *status quo* with a deadline of a day or so.

25 I would also make the observation that this is a very

1 unusual application for a TRO. I thought that lawyers felt the
2 only time they could file an application for a TRO was on Friday
3 afternoon. This is certainly an exception, one of the few that I
4 have seen filed on a Monday morning, but it's awfully nice to have
5 the luxury of having a little more time to think about things.

6 MR. MCDONALD: The clerk's office was equally pleased.

7 THE COURT: No doubt. No doubt.

8 Let's just have a get-acquainted sort of discussion about
9 this case. I have had a chance to scan some of the documents, but
10 let's go around the table and give counsel the opportunity to tell
11 me what they believe this case is all about. Why don't we start
12 with Mr. English.

13 MR. ENGLISH: Thank you, Your Honor, and forgive me and
14 maybe there is some confusion that erupted from the filing
15 yesterday, but this is really an application for preliminary
16 injunction. There is actually no application for a temporary
17 restraining order. That may or may not be the last thing we all
18 agree on today, but it's a preliminary injunction.

19 THE COURT: Very well.

20 MR. ENGLISH: I will get to the timing issue in a moment.
21 While we don't need anything today, I think there is a real need
22 for relief very soon.

23 Your Honor, this case is about the free speech rights of
24 commercial entities both to speak to their consumers and consumers
25 to receive speech about a technology that, while it has been

1 approved for 14 years, has not been without controversy. And the
2 technology, what they call rbST, recombinant bovine somatotropin,
3 while it has been around for 14 years, there has also been
4 labeling around products that voluntarily speak to the concept
5 that various entities, such as Ben & Jerry's, do not accept milk
6 from dairy farmers that use rbST in the treatment of their cows.
7 And for 14 years --

8 THE COURT: Is the purpose of it to increase milk
9 production?

10 MR. ENGLISH: The technology's purpose is that it results
11 in increased milk production under certain circumstances.

12 THE COURT: All right.

13 MR. ENGLISH: Again, it's not without controversy. IDFA
14 for its part is a supporter of the use of technologies. That's
15 not the issue as far as IDFA is concerned. The issue for IDFA is
16 many of its members, because of consumer demands, wished to tell
17 their consumers that they do not receive milk from cows that have
18 been treated with the technology.

19 And that kind of labeling issue has been around since FDA
20 approved the technology. The same day they approved it, they
21 literally issued guidance about how one could label. And that
22 labeling has grown up over 14 years with some state action but
23 largely the FDA guidance.

24 And suddenly, Ohio has stepped into this situation, first
25 with an emergency rule and then a rule that is effective September

1 19 of this year, and has effectively changed the landscape for all
2 of these labels.

3 The FDA guidance states that it may be important to have
4 a disclaimer if you say that you do not use rbGH or rbST. And to
5 date, no one has said that disclaimer language must be at the same
6 level of the claim, our cows are not treated with rbST, and then
7 there is the FDA disclaimer. In most instances, as the FDA itself
8 has indicated, that is connected by an asterisk, and it is
9 readable.

10 But Ohio has said that that disclaimer must be contiguous
11 with the claim. They have also indicated that you cannot say, no
12 rbST, even if you similarly at the same time make the production
13 claim that, our cows are not treated with rbST, even though that
14 is also standard in the industry, has been standard now for 14
15 years.

16 But literally what has happened here, and the reason why
17 there is urgency, is that Ohio chose to say no to a number of
18 claims, even though consumers have had these claims for 14 years.
19 There have been claims of this nature in Ohio for 14 years. Ohio
20 now claims that consumers are misled or potentially misled.

21 Our view of that is quite clear. The First Amendment
22 says that the state may not tell us how to deliver our messages
23 that are accurate and not misleading. The state's response to
24 that is: We will deem certain messages to be misleading.

25 The definition of deem is to have or form an opinion.

1 But that is not what is required under the First Amendment. What
2 is required under the First Amendment is actual evidence, not
3 speculation, that a message is misleading.

4 THE COURT: All right. Well, I think that's a pretty
5 good thumbnail sketch of the plaintiffs' claims.

6 Now you said something that caught my attention. The FDA
7 has spoken on this issue of disclaimer?

8 MR. ENGLISH: FDA expressly at the time that rbGH/rbST
9 was approved indicated that they recognized both consumers would
10 want to know and some entities would wish to speak about the fact
11 that their milk may not be treated.

12 But at the same time FDA said, in order to avoid
13 potential misleading, we suggest that one provide the following
14 disclaimer, that there is no significant difference been shown
15 between cows treated with rbST and those cows that have not been
16 treated with rbST.

17 But subsequent to that, a year later, when asked by New
18 York, FDA says, we have never said that statement is mandatory.
19 There are circumstances in which a claim of no use of rbST would
20 not be misleading without the statement. So it's not even, in our
21 view, a mandatory statement.

22 And now Ohio is saying, not only are we going to make it
23 mandatory, we are going to tell you where to put it. We're going
24 to tell you what size it should be in. We're going to tell you
25 what color it should be --

1 THE COURT: Now I noticed in reviewing the papers that
2 have been filed a reference to a federal -- I don't know whether
3 this would be correct to call it a federal code, but a federal
4 framework of statutory regulations for organic food products.

5 MR. ENGLISH: And I would hand off to Mr. Sunshine for
6 that, Your Honor.

7 THE COURT: All right. Mr. Sunshine, tell me about that
8 and how that relates to this case.

9 MR. SUNSHINE: Thank you, Your Honor. We are a little
10 bit different from Mr. English's client, which is the nonorganic
11 industry, in that the organic industry since 1990 has been
12 regulated by an act called the Organic Foods Production Act. And
13 then subsequently that series of 600 or so regulations, known as
14 the National Organic Program, all of which are designed to
15 regulate the organic industry on the federal level -- what the
16 brief history is that the organic industry had been regulated on a
17 piecemeal basis throughout the country by states. It didn't work.
18 There needed to be standards, federal standards, or Congress
19 decided there needed to be federal standards, and those were
20 passed, like I said, in 1990 with regulations to follow.

21 So for a number of years the organic industry has been
22 regulated carefully, aggressively, systematically by the federal
23 government. In order to be labeled organic, you must go through a
24 careful accreditation and certification process, constant
25 regulation by the federal government --

1 THE COURT: Does this Organic Foods Production Act
2 include labeling?

3 MR. SUNSHINE: Yes.

4 THE COURT: Does it specifically include ingredients
5 labeling?

6 MR. SUNSHINE: Yes, absolutely it does. Yes, it does.

7 THE COURT: Does it address the issue of labeling of milk
8 with respect to these substances that Mr. English just told us
9 about?

10 MR. SUNSHINE: Well, we believe at least by implication
11 it does, if not expressly, because, very simply, in order to be
12 labeled organic, you must go through this accreditation process
13 which includes not being able to use rbST. You can't use rbST for
14 it to be labeled organic. So the fact that you are labeled
15 organic is --

16 THE COURT: So the use of rbST is mentioned in the
17 federal act or regulations?

18 MR. SUNSHINE: Yes, added artificial hormones and, I
19 believe, rbST itself.

20 THE COURT: Does the federal act or any of its
21 regulations specifically deal with product claims and advertising?

22 MR. SUNSHINE: The act deals with labeling. And it does
23 regulate how the organic industry labels.

24 THE COURT: All right.

25 MR. SUNSHINE: So our main argument -- our first argument

1 in our papers, for example, is preemption, federal preemption. We
2 are already regulated by the federal government. And implicitly
3 in the statute, the statute is designed to prevent states like
4 Ohio from taking these extra measures to try to regulate organics
5 when we are already regulated by the federal government.

6 THE COURT: All right.

7 MR. SUNSHINE: And furthermore, we also have the same
8 First Amendment argument certainly that Mr. English does, as well
9 as, I'm not sure he mentioned, the commerce clause argument, but
10 it is also a fundamental Constitutional right that we feel is
11 being violated by requiring different labeling in Ohio from states
12 surrounding.

13 THE COURT: Have any other states gotten into this issue
14 of labeling with these substances?

15 MR. ENGLISH: Yes, Your Honor. From day one a number of
16 states got involved, some states on the exact opposite side here,
17 that is to say Vermont was the first state, and it had two pieces
18 to its original legislation. One piece is what's in effect today,
19 which expressly permits voluntary claims of the nature that are on
20 the labels that Ohio says you may not make. For instance, no
21 rbST, our cows are not treated with, that's expressly in the
22 Vermont statute, also expressly in Minnesota and Wisconsin.
23 Alaska also has a provision, and Maine has the Maine real seal
24 that is based on the same concept.

25 Vermont went a step further. Vermont said, if your milk

1 comes from cows treated with rbST, we are going to require you,
2 the milk processor, to label that your milk has come from cows
3 treated with rbST.

4 And the International Dairy Association filed a lawsuit
5 on First Amendment grounds, among others, against Vermont and
6 prevailed before the Second Circuit on that issue, that they were
7 being forced to speak. And we submit that this case, that's the
8 IDFA *versus Amestoy* case in our papers, we submit that this case
9 is virtually identical to this case in that our members are being
10 forced to say the disclaimer in the way that the state declares.

11 Now after that, Your Honor, Illinois entered the realm to
12 some extent, and it banned labeling. It was sued by Ben &
13 Jerry's, Whole Foods and others. The case settled relatively
14 quickly with an issuance of an Illinois regulation which is not as
15 restrictive as the Ohio regulation. It is identical in one
16 respect on its face, that it bans claims of no rbST; but in
17 practice it has not actually banned that claim, and we have that
18 in our declaration, Shamrock declaration, that in fact the no rbST
19 claim was permitted by Illinois.

20 Most recently -- There are a number of states that are
21 looking at this. I mean, frankly, Your Honor, what this gets to
22 is, the unstate of the clear purpose here, is to protect rbGH
23 producers and the company that makes rbGH, Monsanto Company, from
24 competition from non-rbGH which is not a legitimate state
25 interest.

1 A number of states have been looking at the issue over
2 the last twelve months for the reason that critical mass has been
3 achieved. Consumer demands are such that the product is just not
4 welcome to consumers. And a number of processors declared that
5 they have to have their milk from cows not treated with rbST.
6 That was February 1. The director's emergency rule was February
7 8.

8 In the interim, Pennsylvania issued an absolute ban
9 October 29 of last year, I believe it was, certainly late October,
10 IDFA and others, frankly, threatened suit, ultimately resolved the
11 matter with Pennsylvania. Pennsylvania withdrew their ban and
12 ended up with a provision which is now being applied, and how it's
13 being applied may be a different issue, but on its face is less
14 restrictive than the Ohio provision. In fact, Pennsylvania would
15 permit a claim of no rbST, our cows are not treated with rbST,
16 from a plant located in Erie, Pennsylvania. But if this product
17 comes into Ohio after September 19, it would be banned. And at
18 some point I would like to talk about the timing issue here.

19 So, yes, a lot of states have acted. But the general
20 issue over 14 years has been to permit, not restrict, the product.

21 THE COURT: Have the plaintiffs in this case had the
22 opportunity to have input with the Ohio Department of Agriculture
23 and/or negotiations with the Ohio Department of Agriculture about
24 the rule?

25 MR. ENGLISH: After the emergency rule was issued, a lot

1 of people reacted. The director, quite properly -- and we
2 appreciate the fact -- had two hearings in March and April. The
3 transcripts are part -- the largest part of the volume of the
4 exhibits, 250 pages or so. And the International Dairy Foods
5 Association, from that part -- Mr. Sunshine can speak to OTA --
6 had an opportunity to speak.

7 A number of the arguments that are made in our papers
8 today are not surprising because they were found in that material.
9 Very, very small changes were made in the emergency rule, but it
10 did not affect its overall impact. But, yes, there was an
11 opportunity to be heard. IDFA was heard, although we don't
12 believe we were really heard in the sense that action was taken on
13 that.

14 And part of that concern that IDFA has is even before the
15 emergency rule, Ohio had in existence authority to act about any
16 misleading labels. There is existing authority under the federal
17 standards, which is the FDA guidance, to act.

18 We are unaware of any significant effort undertaken --
19 First of all, we are unaware of consumer complaints that preceded
20 the emergency rule. We are unaware of enforcement attempted under
21 the existing regulations. And we are unaware of ineffective
22 enforcement. So then why we are suddenly having this?

23 THE COURT: All right. Mr. Sunshine, do you want to add
24 anything --

25 MR. SUNSHINE: Only that we also participated in -- We

1 testified at the hearing. We have had informal discussions, my
2 client has had informal discussions, with Mr. Patterson. So we
3 have attempted to discuss the issues with the state. They have
4 not, obviously, resulted in a result that we're comfortable with.

5 THE COURT: Well, let's hear the other side's story.

6 MR. PATTERSON: Thank you, Your Honor. I will try to
7 give you a brief rundown, more or less, in a chronological time
8 frame here of what took place.

9 First, with regard to the FDA guidance which was in place
10 in the 1990s, the FDA guidance is, by its very terms, guidance.
11 It's voluntary guidelines. But the guidance from FDA does
12 specifically make mention of the fact that FDA is relying upon the
13 states to enforce any laws with regard to misleading claims on
14 labels.

15 So not only is there no preemption on the part of FDA on
16 this issue, but in fact the opposite, the explicit reliance on the
17 states to act within their own borders. The language which ODA
18 ultimately adopted is virtually the same as the federal suggested
19 language in the FDA guidance.

With regard to the Organic Foods Production Act, which was also mentioned a few minutes ago, that has been on the books for a while. I respectfully disagree with plaintiffs' counsel in saying that there is any preemption in the federal act with regard to these labels. The Organic Foods Production Act deals specifically with the basis for which one may use the term

1 "organic." All of the terms reference what needs to be done in
2 order to qualify either under a USDA-approved program or a
3 state-approved program that meets USDA guidelines to use that term
4 "organic."

5 There is no provision in the Organic Foods Production Act
6 that in any way impedes or preempts state regulation of other
7 label claims that may be misleading, such as the one that's the
8 subject of this rule. So ODA would disagree that there is any
9 basis for preemption because of the OFPA with regard to the rule
10 that's in dispute in both of these cases.

11 When this issue became, I guess the way to put it, an
12 important issue within the industry, Pennsylvania had already
13 enacted a rule. This became an issue of concern in Ohio where it
14 became obvious that there was a request among certain consumers to
15 have access to this information about rbST in milk. There were
16 also concerns raised with regard to the industry as to what the
17 standards would be.

18 I agree wholeheartedly that ODA has had statutory
19 authority to prohibit misleading statements on labels. This rule
20 is actually enacted to implement that statutory authority in a
21 area where there is particular need, given market circumstances,
22 to give guidance to the industry about what exactly is permitted
23 with regard to the use of rbST.

24 There were actually extensive hearings, formal and
25 informal, that ODA conducted before this rule was enacted. Before

1 even the emergency rule was enacted by the governor, the Director
2 of Agriculture appointed an advisory committee that covered a
3 broad spectrum of points of view, including dairy producers,
4 processors, consumers, people involved in organic production
5 across the board. And the advisory committee held, I believe,
6 three sessions that were open to the public, invited comment and
7 listened to comment from the public, anyone that wished to provide
8 information to the advisory committee, that was conducted before
9 any emergency rule was enacted.

10 Once the emergency rule was enacted, ODA actually
11 conducted two hearings. There was the initial rule that was filed
12 in February. A public hearing was held pursuant to Ohio Revised
13 Code 119. And ODA received many comments from many, many
14 different sectors of the public in response to that rule, both
15 oral comments at the hearing and also written comments that were
16 submitted.

17 Following that hearing, the director decided that a
18 revised rule would be submitted to take into consideration some of
19 the points that were raised in those comments. So the revised
20 rule was submitted. Another public hearing was held. More
21 comments were submitted with regard to that rule.

22 In addition to those formal hearings, if you will, the
23 department has also engaged in informal discussions directly with
24 representatives of the International Dairy Foods Association and
25 the governor's council. I have also participated in some fairly

1 extensive telephone conversations with the representative of the
2 Organic Trade Association.

Finally, the rule, when it came up for consideration before JCARR in the state legislature, it was not under the consent docket. It was set on the regular docket for comment. And JCARR also heard extensive comments with regard to the rule and ODA's authority to issue this rule in connection with its adoption.

9 THE COURT: JCARR?

10 MR. PATTERSON: I'm sorry, the Joint Committee on
11 Administrative Rule Review. I believe that's what it stands for.
12 That is the legislative committee that reviews every
13 administrative rule to make sure that it's within the authority of
14 the agency to enact it.

15 That process is often done by agreement. But in this
16 case, because there were individuals that wished to speak to the
17 rule, it was on the full hearing docket. And the committee heard
18 two or three hours, I believe, of comments. So there has been an
19 extensive opportunity for public comment throughout this process.

20 JCARR did not see any legal defect with the rule and took
21 no action to hold it up, which is what they would have done if
22 they felt it was not within ODA's jurisdiction to enact it. So at
23 this time the rule was formally adopted, I believe on May 22; and
24 pursuant to its terms, it would require compliance 120 days
25 thereafter, which would be September 19.

1 The 120 days is actually a figure that was proposed by
2 industry representatives as a reasonable time period for them to
3 have to come into compliance in terms of design changes,
4 production, making all the necessary arrangements to come into
5 compliance with the rule.

6 I would like to respond to one other -- or two other
7 comments that were raised by plaintiffs' counsel, if I could. One
8 is with regard to actions taken by other states. Pennsylvania,
9 for example, was a good example of. Pennsylvania's rule is
10 actually quite similar to Ohio's rule. It has a few differences.
11 They do not require that the disclaimer language be the same color
12 as the claim; whereas Ohio requires same font size, style and
13 color. I don't believe Pennsylvania requires color. Pennsylvania
14 does not require the disclaimer be contiguous, but it must be on
15 the same label and in the same view as the claim. And I believe
16 Pennsylvania does not require the disclaimer language for
17 certified producers, which may be a meaningful distinction in
18 terms of the OTA case. I don't know if it's a meaningful
19 distinction with regard to the IDFA case.

20 In other cases states have enacted or in the process of
21 looking at similar regulations. Kansas, I believe, is currently
22 considering a rule which would be not only as strict but more
23 strict than Ohio's rule, I believe, in that it would require the
24 disclaimer language to be the same font size, not just half the
25 same font as the claim. I believe Utah, New Jersey and other

1 states are currently looking at the rule.

2 Your Honor, the states are all over the board on this
3 issue, and this may be good policy for the Congress to step in and
4 to explicitly adopt a federal guideline which regulates claims of
5 this type with regard to rbST. But Congress has chosen not to do
6 that to this point. And I believe the evidence will demonstrate
7 in this case that OFPA, as I said, does not preempt this issue by
8 the state.

9 So at this point the system that's in place is for each
10 state to make a determination regarding labels for products being
11 offered for sale within that state as to what would be misleading
12 or what is required to do that.

13 I would say, Your Honor, that the intent behind this rule
14 was to try to accommodate the interests of both consumers that
15 wanted to have access to this information and to producers that
16 wanted to make sure that the information was accurate and was not
17 misleading. So the rule is an attempt to accommodate both of
18 those interests, to give consumers access to accurate information
19 regarding the production of milk.

20 But given the fact that there is no credible scientific
21 evidence that there is any difference between milk produced from
22 rbST-treated cows and cows that have not been treated with rbST,
23 as referenced in the FDA interim guidance, ODA determined that a
24 label without any disclaimer language with regard to rbST does
25 have the potential to mislead consumers if that language is not

1 included.

2 THE COURT: You have just touched on something that I
3 wondered about as I did my preliminary reading, and that was
4 whether or not the rbST that's given to the cows actually ends up
5 in the milk?

6 MR. PATTERSON: Your Honor, it is not detectable in any
7 practical way in the testing of the milk. Cows naturally produce
8 bST, bovine somatotropin. All milk has hormones in it. And rbST
9 is a synthetic version of a hormone that is already present in the
10 cows, and that hormone is going to be present in the milk
11 regardless.

12 A few of the members of the advisory committee that I
13 mentioned earlier have scientific credentials from Ohio State, and
14 I can't remember exactly who all was on that committee, but those
15 scientific issues were discussed at some length in the advisory
16 committee, and I believe that there is a consensus that there is
17 no practical means to test milk to detect rbST.

18 I think it's theoretically conceivable to do it if you
19 spend enough money and do mass spectrometry and so forth to
20 distinguish rbST from bST. There is, I believe, a very slightly
21 altered level of bST and rbST in milk from cows that have been
22 treated with rbST. The scientific evidence is that it is a
23 statistically insignificant difference in the milk in that it is
24 not possible to distinguish between bST and rbST in any practical
25 way nor that there is any health consequence or health difference

1 whatever.

2 And I appreciate there is some dispute I believe between
3 certain members of the scientific community that, I assume, that
4 the plaintiffs are expecting to testify, having read their
5 pleadings, trying to challenge the FDA's determination that there
6 is no scientific basis to see a difference between the milk, and
7 that may be a factual issue that would have to be presented to
8 this Court.

9 But from what ODA has learned from witnesses in the
10 hearing process and the comment process is that the FDA's
11 determination is correct, that there is no credible scientific
12 evidence there is any difference in the milk.

13 THE COURT: Thank you.

14 MR. PATTERSON: If I might, Your Honor, one final
15 comment. You had asked about -- or actually I think this was a
16 comment made by IDFA's counsel, and that is with regard to
17 Monsanto's involvement. I simply wanted to clarify. I think
18 there is a misperception among certain members of the public that
19 Monsanto, who produces really the main, possibly the only, form of
20 rbST that is commercially used, that Monsanto is somehow behind an
21 effort among the states to try to restrict rbST-free claims of
22 milk. And that's why I tried to take some pains to go through the
23 hearing process that took place to make it clear that the
24 department heard testimony from many different parts of the
25 public.

1 Monsanto did have a representative at one or two of the
2 hearings. Monsanto did produce comments. But the Court will not
3 hear any evidence in this case that Monsanto is behind an effort
4 by ODA to adopt this rule or to change the label requirements
5 because no such evidence exists. And I don't know what efforts
6 Monsanto may have made in terms of lobbying other states in terms
7 of what rules might be appropriate, but there will not be any
8 evidence that Monsanto is in any way pulling any strings or
9 manipulating the regulatory process in Ohio in any respect.

10 THE COURT: All right. Thank you, Mr. Patterson.

11 Well, counsel, would either of you like to respond to any
12 of the things that Mr. Patterson just said?

13 MR. ENGLISH: Your Honor, I would like respond to one
14 issue, and partly because you raised it and partly because of the
15 answer. Again, IDFA may be different from OTA because the organic
16 foods do have a different point of view on this. IDFA is on
17 public record as supporting the use of approved technologies.
18 That's not the issue.

19 There may turn out to be some evidence about whether
20 there are tests, how practical they are, how expensive they are.
21 They are -- Apparently, the standard practice to protect
22 intellectual property is to make a deviation in at least one note
23 in the DNA in the product so one can know whether it's being used.
24 But that's not the issue. I think it is a bit of a red herring.

25 The question here is: Are IDFA's members free to speak

1 in a manner in which they choose based upon FDA guidance? And
2 what is not proven, because the director in the First Amendment
3 issues has the burden of proving that it is either factually
4 misleading or potentially misleading, but it may not be based on
5 speculation.

6 The question of whether or not there is an actual
7 difference or health difference is irrelevant if American
8 consumers want the product. That's what the First Amendment is
9 about.

10 And so we think that is a critical difference, that the
11 consumers have spoken with their wallets --

12 THE COUR: Even if they want it as a result of some
13 misconception?

14 MR. ENGLISH: If it's their misconception, that's what
15 our country allows -- our country allows our consumers to have
16 misconceptions. We have all sorts of products out there locally
17 produced, Ohio produced. What is the relevance -- Well, a
18 consumer wants to support the Ohio economy. Consumers don't want
19 their cows treated with rbST for whatever reason consumers want.
20 That's not for the government to say is right or wrong. That's
21 what the First Amendment is about.

22 I do want to get back to the commerce clause issue for a
23 moment because we are being asked to give up our clients' speech
24 rights not only in Ohio but outside Ohio. The director had
25 evidence at the hearing presented by IDFA and others, but also

1 within this documentation now, that there is no way in the modern
2 distribution system for milk -- to distinguish between milk that
3 is sold in Pennsylvania or Ohio or Minnesota or anywhere else.
4 The practical consequence is you either have to give up your
5 speech as HD Hood did in the sale of their Kemps product here in
6 Ohio. Since the rule has been issued, they have stopped selling
7 specific chocolate milk with that label. Consumers have lost that
8 opportunity in Ohio because of the rule. But anything like
9 Shamrock or Tillamook from Oregon and Arizona, they don't have
10 that choice. They have a national product line. They have a
11 national brand. They are going to have to decide whether they are
12 going to abide by the Ohio rule and give up their speech rights in
13 Arizona and in Oregon and in every other state, or what they're
14 going to do.

15 And that comes back to the timing issue, and I appreciate
16 very much the idea of 120 days. And one of the questions here --
17 I am confident they can't probably resolve it today -- but we
18 literally are in a situation where today entities are making
19 decisions, if you read the declaration from Shamrock and Kraft,
20 they are already making decisions that are very costly. The
21 director pulled a number out of the air, as near as I could tell,
22 of \$250 to \$300 for changing a label. Ben & Jerry's says it is
23 going to cost \$250,000 for them to change all their labels, labels
24 that have been used in Ohio since 1996, and now they're suddenly
25 unable to use. There are some real costs, none of which can be

1 recovered under the Eleventh Amendment, and some real irreparable
2 harm that's going to happen immediately.

3 So we need to schedule --

4 THE COURT: What have they done in other states that have
5 legislated in this area and required labeling?

6 MR. ENGLISH: Well, no other state has gone to this
7 point. This gets to the point that whoever gets this first --

8 THE COURT: They had to -- I mean if they are selling
9 milk in those states like Pennsylvania, they had to change labels
10 there, didn't they?

11 MR. ENGLISH: Some labels have been changed in
12 Pennsylvania, to my knowledge, very minimally. The national label
13 of Shamrock is still being sold in Pennsylvania. I don't think
14 this has resulted in anything else there. Illinois has done the
15 same with the national label of Shamrock. It said, okay, because
16 Arizona worked to develop this label, we are going to allow it,
17 even though under our provision, which is identical to the Ohio
18 rule for no rbST, even though we don't like it, we are going to
19 allow it. We are not going to interfere with interstate commerce.

20 THE COURT: Mr. Sunshine, any comments?

21 MR. SUNSHINE: Lastly, back to preemption for one moment,
22 I want to emphasize there is a certification process under the
23 organic -- the federal organic food act. In order to be deemed
24 organic, my clients have gone through an extensive process --

25 THE COURT: Have any courts ruled on the preemption

1 argument in other states where there has been action taken?

2 MR. SUNSHINE: No. The argument that I'm making has not
3 been made. And in fact, there is no case that holds, that we
4 believe we have looked at, and we have got other clients, there is
5 no case that holds that the National Organic Foods Production Act
6 does preempt state rule probably because in the program, the
7 regulations have only been in existence since 2002, this kind of
8 issue hasn't come up.

9 THE COURT: Has there been litigation in the other states
10 that we have been talking about?

11 MR. ENGLISH: There was litigation in Illinois bought by
12 Ben & Jerry's, but it was frontally resolved. Monsanto brought --

13 THE COURT: Any decisions rendered by the courts there?

14 MR. ENGLISH: It was a party decision, jurisdiction over
15 the city officials of Chicago.

16 Similarly, Monsanto sued Oakhurst in federal court in
17 Boston or Maine -- no, the lawsuit was brought in Boston,
18 Massachusetts, and there were two issues raised in the case. The
19 preliminary injunction was denied but not a lengthy decision, just
20 a denial. And then there was a venue question, and that case
21 settled. And as a result of the settlement, Monsanto allowed
22 Oakhurst to continue using the label.

23 THE COURT: No court, state or federal, has ruled on the
24 issue with respect to rbST in any, that you are aware of, any
25 case?

1 MR. ENGLISH: The *Amestoy* case, the case in Vermont,
2 where it required the processor to speak if their cows -- labels
3 that their cows were treated with rbST.

4 THE COURT: What happened there?

5 MR. ENGLISH: Again, the case in Vermont was in two
6 pieces, and the piece that was actually in litigation was a
7 requirement by Vermont that if your cows were -- if your milk was
8 received from cows that were treated with rbST, you had to have a
9 label that said, our milk comes from cows that were treated with
10 rbST.

11 And the IDFA filed a lawsuit. The district court denied
12 injunctive relief. The Second Circuit reversed it. That case had
13 two pieces to it. It had the First Amendment piece, and it had
14 another piece. The other piece wasn't ruled on. It was just the
15 First Amendment. And the Second Circuit ruled that Vermont had no
16 power to require that speech.

17 But it went beyond, and it was *dicta* -- I think it was a
18 fascinating statement -- we understand consumers want and have a
19 need for this information. And we respectfully suggest that the
20 manufacturer provide that information voluntarily on labels. And
21 we encourage consumers to vote with their pocketbooks based on --

22 THE COURT: Is this Vermont Second Circuit case the
23 only --

24 MR. ENGLISH: The only decision that I am aware of on the
25 merits, 1996.

1 THE COURT: Very good. Well, your comments have been
2 helpful, counsel.

3 Let's talk about what we need to do to get this case
4 ready for a final hearing. And let's just go around the table
5 again, starting with Mr. English.

6 MR. ENGLISH: Well, again, Your Honor, the critical point
7 for IDFA -- and I don't want to speak for OTA, but Mr. Sunshine
8 won't disagree with me -- we need something to happen before the
9 September 19 enforcement date, which has been indicated by counsel
10 is not a date that is --

11 THE COURT: Well, we'll talk about that. First, I would
12 like to know what the parties think I will need to make a decision
13 either preliminary or final. And I will tell you this. I think
14 that I would, if at all possible, like to schedule preparations so
15 the Court only needs to have one hearing in this case. And it
16 would be my goal to consolidate the hearing on preliminary relief
17 with the hearing on final relief. What will I need to do that?

18 MR. ENGLISH: Thank you, Your Honor. I apologize if I
19 went off. And by the way, counsel had brief discussions before
20 you arrived, and we may not have covered all the waterfront, but
21 we covered a fair amount of the waterfront. Leaving aside the
22 timing issue for one moment, we, for our part, may want to take
23 one or two depositions. We haven't decided that. We certainly
24 wouldn't make it lengthy. I think certainly with, the term used
25 was critical decision maker, but probably one or two

1 depositions --

2 THE COURT: These would be officials in the Ohio
3 Department of Agriculture.

4 MR. ENGLISH: Now there was some discussion of witnesses
5 with the department. It may be that as a result of putting forth
6 witnesses that we don't know of yet, that we may have to do
7 something more. But based on what we know about the case today,
8 that would be the situation from our perspective.

9 We believe that beyond that, we have prepared a fairly
10 complete case. Certainly we would like the opportunity to reply
11 to any opposition that was filed. But we believe we have already
12 presented a fairly complete case. This is a facial challenge.
13 And as such, it has a lot of issues that are already out there
14 that don't need to be further resolved.

15 Obviously, the department has a rule making. The
16 transcripts are here. We have 3,000 pages of exhibits that we can
17 get, that we can get to. So there's not a whole lot more.

18 THE COURT: All right. Mr. Sunshine?

19 MR. SUNSHINE: Well, for example, the preemption
20 argument, and that is the one that I have differently from
21 Mr. English, I believe Your Honor could decide that as a legal
22 matter.

23 THE COURT: As a legal matter.

24 MR. SUNSHINE: It really does not involve a tremendous
25 factual workup.

1 THE COURT: Would either of the plaintiffs expect to call
2 expert witnesses in a final hearing?

3 MR. SUNSHINE: Perhaps.

4 THE COURT: How many? And who?

5 MR. SUNSHINE: Probably only on the issue -- and I'm
6 speaking a little bit off the top of my head, I haven't given it a
7 lot of thought yet -- but I believe on the consumer issue it is
8 quite possible we would want to put forth an expert on what
9 consumers really do want and really those -- There was a statement
10 made by Mr. Patterson that consumer needs and desires were taken
11 into account. We may have something to say about that, and we may
12 put an expert in on that.

13 MR. ENGLISH: I think in addition to that, there may be
14 *amici* filing from consumer groups. I believe one or more entities
15 will seek the opportunity to file just a brief --

16 THE COURT: All right.

17 MR. ENGLISH: -- that could be a result of that.

18 THE COURT: You don't expect to call any experts, I take
19 it?

20 MR. ENGLISH: Other than discussed by Mr. Sunshine.

21 THE COURT: Consumer experts who will say what they think
22 consumers want --

23 MR. ENGLISH: Correct --

24 THE COURT: -- based on some kind of research, I suppose,
25 market surveys, whatever.

1 What says the State of Ohio?

2 MR. PATTERSON: We have been handicapped. We just got
3 these pleadings yesterday. So I have not had a chance to discuss
4 this with the director or the dairy division so I will have to
5 shoot from the hip on what we expect we will probably need to do.

6 This case is largely a case of legal disputes. There
7 will be some extensive legal arguments, I believe, on the First
8 Amendment issue with regard to the *Central Hudson* standards. I
9 believe there are some extensive legal arguments made with regard
10 to both the preemption issue and with regard to the issue of
11 interstate commerce.

12 I do expect some factual testimony to be required, which
13 may or may not involve experts outside of the Department of
14 Agriculture. I believe that there probably will be the need for
15 at least one expert witness from outside the department to deal
16 with some of the science issues related to rbST, what it means or
17 doesn't mean in the production of milk and why, from a scientific
18 standpoint, it has the clear potential to mislead consumers.

19 I, frankly, am not able to answer Your Honor what
20 additional expert witnesses may be required. And I have
21 represented to counsel before we started the formal conference
22 this morning that I would try to notify them as soon as I possibly
23 could who the department would anticipate calling so that if they
24 do wish to take depositions, that can be done in an orderly
25 fashion.

1 THE COURT: All right. Do you see the need for any
2 depositions?

3 MR. PATTERSON: I am not sure, Your Honor. I believe
4 there may be the need for at least one or two depositions. There
5 were a number of affidavits filed in support of the motion for
6 preliminary injunction, and I anticipate that it may be necessary
7 to take the depositions of one or more of the individuals that
8 have submitted those declarations.

9 THE COURT: All right. Well, as you pointed out, some of
10 these issues -- both sides have pointed out that some of the
11 issues may be purely legal issues.

12 Have you thought about how you will be responding to the
13 complaint? Do you expect a motion to dismiss? Will there be a
14 motion for summary judgment? How can we get these legal issues
15 before the Court in the most efficient manner?

16 Let's go around the table again. Mr. English?

17 MR. ENGLISH: Well, we believe they are before the Court
18 in the form of a motion for preliminary injunction.

19 THE COURT: All right.

20 MR. ENGLISH: Which under rule 65, as you yourself have
21 indicated, consolidated with a final hearing on the merits, that's
22 where we think the legal issues can be resolved. We think it is
23 very largely legal. We think there may be some factual red
24 herrings about what the science is. We think that's irrelevant.
25 But be that as it may, we think that it's before the Court.

1 THE COURT: I appreciate that.

2 Mr. Sunshine?

3 MR. SUNSHINE: I don't disagree at all. The only thing
4 is, I respect the fact that Mr. Patterson has had a day or even
5 less to review the papers. I don't think we are taking on the
6 science issue directly as Mr. Patterson seemed to indicate. I do
7 not believe that this case will involve scientific experts,
8 challenges as to whether or not rbST harms humans or even cows.

9 THE COURT: I wonder if it might make sense for both
10 sides to consider to what extent stipulations can be made. That
11 would focus the issues and perhaps even eliminate the need for
12 some of this expert testimony. Perhaps all of it. I don't know.
13 It seems that that might be a possibility.

14 Well, as counsel for the state has just pointed out, they
15 have just received the papers. You folks have been working on
16 this for some time. This probably didn't come as a complete
17 surprise to them, though? But they do need time to sort things
18 out.

19 And I'm thinking maybe we ought to have another status
20 conference sometime very soon. And perhaps then the state will be
21 in a better position to respond to my questions about discovery
22 and experts and so forth. So let's just look at the calendar and
23 see how we might do that.

24 Mr. Patterson?

25 MR. PATTERSON: If I might, with regard to the scheduling

1 issue, we have had some informal discussions before we began this
2 morning's conference. And if I might, just a couple of things.

3 First of all, both plaintiffs' counsel courteously agreed with me
4 to extend a 20-day request for answer deadline to the complaint.

5 Your Honor, at this point I'm not sure whether the department
6 would file any dispositive motions with regard to any of the
7 counts in the complaint. I think it's possible, but it's too
8 early for me to advise my client that would be an appropriate
9 move.

10 Unfortunately, this being the beginning of July, we have
11 some vacation scheduling issues that I have mentioned to
12 plaintiffs' counsel, most specifically being that I understand
13 Mr. Cole is going to be gone next week. And, Your Honor, I have
14 had a longstanding family vacation planned from July 14 through
15 the 25th. So I would respectfully ask if we could stay away from
16 my vacation time in terms of court appointments, I will certainly
17 give this case the highest priority that I can and accommodate the
18 Court's convenience with regard to any conferences and any
19 deadlines that the Court would wish to set on this case.

20 I have also mentioned to plaintiffs' counsel it is not
21 the department's intent to in any way put the plaintiffs in a
22 position where they are dealing with an eleventh-hour ruling with
23 regard to compliance with the rule. And the September 19 deadline
24 for compliance that came up is based really on just the automatic
25 enforcement of a 120-day deadline in the enforcement of the rule.

1 By the same token, however, I certainly would appreciate
2 an opportunity to review the pleadings in depth and also have
3 in-depth discussions with my client in terms of what their
4 litigation strategy would be. And I will make every effort to see
5 what we can work out as far as stipulations of facts, as the Court
6 suggested, because I think we may be able to cut back
7 significantly the amount of time that we would take of the Court
8 in hearing on factual issues that may not in fact be the subject
9 of *bona fide* disputes. So we will make every effort to work out
10 stipulations.

11 THE COURT: Well, I'm wondering -- I'm looking at the
12 date of July 11 for a possible further status conference with the
13 hope that we might have perhaps an agreed schedule in place by
14 that date. What do you think, counsel? Do you think that that
15 will give you enough time to get together, discuss these matters
16 and decide how much time you will need to complete discovery in
17 the case and --

18 MR. PATTERSON: I will make myself available on the 11th,
19 Your Honor. The one question that I have, this goes to my point
20 about giving the plaintiffs enough time to prepare, the question
21 was asked of me to raise with my client whether ODA would be
22 willing to consider any sort of postponement of the enforcement
23 deadline of September 19 in this case, which I mentioned to
24 counsel I will certainly discuss with the director.

25 I guess one question that we all had, perhaps, with the

1 Court would be: Realistically, what sort of time frame would be
2 available to the Court both in terms of convening a hearing and
3 how much time the Court would anticipate it would take to render a
4 decision in this case? That would give us a little better idea as
5 to when we might be able to stipulate to a hearing taking place
6 before you, Your Honor.

12 I think our goal should be to get on track for completing
13 all the necessary preparation, a briefing schedule, if you will,
14 and deadline or cutoff date for discovery, a cutoff date for
15 identifying expert witnesses. Or if you come to me and say, we
16 are going to have a stipulation, obviously that would speed things
17 up.

1 I'm going to be gone for the month of August. After
2 that, we can schedule a hearing in this case any time in
3 September, October, November or in December.

4 MR. PATTERSON: Your Honor, I will represent to the Court
5 and to plaintiffs' counsel that I will speak with my client about
6 the issue of entering into a consent decree that would accommodate
7 the Court's schedule and would also give everyone an opportunity
8 to hear this case and in a deliberate fashion without putting the
9 plaintiffs in the position of being out of compliance.

10 So I can't speak for the director, only the director can,
11 I guess, speak for ODA on that issue, but if it would allow this
12 case to be heard in a complete and a deliberative fashion and
13 protect the plaintiffs from being out of compliance with the rule,
14 I think that's worth considering.

15 THE COURT: I think that is very constructive.

16 MR. ENGLISH: And I thank you very much for that. I want
17 to say if we can't do that because of your schedule, we, for our
18 part, because of the reality, these labels don't just magically
19 appear, there is real artwork that has to be done. That is the
20 reason this cost Ben & Jerry's \$250,000. Some of these labels
21 have to be received from overseas. So we are literally going to
22 say absent some kind of arrangement after September 19, we would
23 need a decision by August 8. Obviously, if it doesn't work for
24 your schedule, then we would certainly work with the defendant on
25 this as much as possible. We really appreciate that, Your Honor,

1 and hopefully we can hear in short order -- it doesn't make a
2 whole lot of sense for these folks spending a lot of money on
3 revised labels when we don't know what the final result is going
4 to be, and they would have to start all over again, and that would
5 be obviously very wasteful of their resources.

6 MR. PATTERSON: There is nothing magic about September
7 19, Your Honor.

8 THE COURT: That's very helpful. But we still need to
9 know how much time will be required to complete whatever discovery
10 will be necessary in this case. We will need to know how long the
11 hearing may take. We will need to know what a realistic deadline
12 is for briefing all the legal issues in this case.

13 When I have all of that in hand, then I will be able to
14 say, okay. We are going to need two days, three days or a week,
15 whatever it may be, for the hearing on this case, and then I can
16 find a time on my calendar when I can fit that in.

17 So is July 11 a realistic date? Or we can look at some
18 later date.

19 MR. PATTERSON: Your Honor, I think July 11 is very
20 realistic for us to hopefully agree to the schedule for all the
21 issues that you have raised.

22 MR. ENGLISH: Yes, thank you, Your Honor. Yes,
23 absolutely.

24 THE COURT: I know -- I realize some folks have come
25 quite a distance for this conference, and I appreciate that very

1 much. However, if you -- if we should be scheduling things at a
2 time when it's just not convenient to make that trip, then you can
3 certainly request the opportunity to participate by way of
4 telephone, and we will hook up that speaker phone, we will put it
5 in the center of the table, and we can plug you in that way, if
6 you desire. So -- and I'm not requiring that you be making this
7 trip every time I schedule something here in our courthouse. You
8 have local counsel, very competent counsel. And you will also
9 have the opportunity to participate directly through the
10 telephone, if you wish to do so.

11 MR. SUNSHINE: Thank you, Your Honor.

12 MR. ENGLISH: Thank you, Your Honor.

13 MR. COLE: Judge, I just have a comment, since we have 20
14 plus 20 to respond, there is also the pending motion for
15 preliminary, since they are accommodating, would we need to file a
16 memo contra to --

17 THE COURT: No. No. You can save your efforts for the
18 briefing on the final hearing.

19 MR. PATTERSON: I realize there is one other technical
20 question, I am not sure, but has there been an order actually
21 consolidating the two cases at this point?

22 THE COURT: I signed an order yesterday and sent it to
23 Judge Smith's chambers. We are -- Our chambers conferred,
24 actually through our law clerks, and determined that the cases are
25 essentially identical and the same issues, and mine was filed

1 first. So under our standard procedure, I will be the presiding
2 judge, and Judge Smith agrees with that, and I assume he will be
3 signing that order today, if he hasn't already signed it.

4 MR. PATTERSON: Thank you, Your Honor.

5 THE COURT: Anything else we can do today?

6 MR. ENGLISH: Not to be hyper technical, and I apologize,
7 but I understand that the goal is not file as a response to the
8 preliminary. But if it turns out that the director, contrary to
9 what probably would be the September 19 deadline --

10 THE COURT: That would change things completely.

11 MR. ENGLISH: I want to be clear --

12 THE COURT: Then we would have to have a hearing before
13 the 19th, and I would have to arrange my schedule for doing that,
14 and it might require us to have bifurcated proceedings, which we
15 hope we don't.

16 MR. PATTERSON: I will accurately convey the Court's
17 comments to my client.

18 THE COURT: All right. Well, what time do you want to
19 get together on Friday, July 11? Morning would be best for me.

20 MR. PATTERSON: I am available. Whatever is convenient.

21 THE COURT: Ten o'clock.

22 MR. SUNSHINE: Ten o'clock is fine by me.

23 MR. PATTERSON: Would it be in this room as well?

24 THE COURT: In this room, yes, indeed.

25 Anything else we can do this morning, counsel?

1 MR. PATTERSON: I think that's everything for us, thank
2 you, Your Honor.

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C E R T I F I C A T E

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I, Laura L. Samuels, do hereby certify that the foregoing is a true and correct transcript of the proceedings before the Honorable James L. Graham, Judge, in the United States District Court, Southern District of Ohio, Eastern Division, on the date indicated, reported by me in shorthand and transcribed by me or under my supervision.

/s/Laura L. Samuels
Laura L. Samuels
Official Federal Court Reporter